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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,424	03/01/2002	Phillip Dan Cook	ISIS-5031	4700

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PHILADELPHIA, PA 19103

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 10/087,424	Applicant(s) COOK, PHILLIP DAN	
	Examiner Maurie G. Baker	Art Unit 1639	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: Please see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 31-50.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION
Attachment

1. Applicant's After Final response filed November 25, 2003 was not found persuasive and thus does not place the case in condition for allowance. The rejections are maintained for reasons of record and the further reasons set forth below.
2. With respect to the written description rejection, claims 31-50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
3. Applicant again argues that the scope of the claimed genus of "purine or pyrimidine heterocyclic scaffold having at least two functionalizable atoms" and "chemical substituents" is not "virtually unlimited" as stated by the examiner. However, as stated in the Final Rejection, there is no indication in the claim of the specific identity, location or attachment of the functionalizable atoms or the specific nature of the chemical substituents; therefore, the number of compounds that would fall within this scope would be extremely large (i.e. "virtually unlimited"). Note that in some claims, the chemical substituents can be attached via a tether moiety, which is another source of almost infinite variation.

4. The examiner's position is that the instant specification discloses only limited examples of carrying out the claimed method and that this disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Applicant argues that the instant specification adequately describes such entities and points to various portions thereof (Response, pages 2-3). Although the specification does describe numerous examples, these examples are directed to a very limited set of molecules and represent only a very limited subset of the claimed genus of "purine or pyrimidine heterocyclic scaffold having at least two functionalizable atoms" and "chemical substituents" (attached either directly or via a tether moiety).

5. Note that a representative number of examples means that the species that are adequately described are representative of the entire genus. When there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. It is deemed that the instant specification lacks adequate support relating to the claimed genus as the species disclosed, while numerous, do not reflect sufficient variety.

6. Applicant also refers to specification definitions for terminology such as "functionalizable atoms" (Response, page 3). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. With respect to the rejection of claims 31, 32, 34-36, 38, 39, 41-43 and 45-49 under 35 U.S.C. 102(a) as being anticipated by Gordeev et al (WO 96/33972), these claims remain rejected. Applicant states that since the Gordeev et al reference “takes a mixture of amino acid precursors and reacts them to produce their respective guanidine derivatives” (Response, page 3, bottom), it does not anticipate the instant claims. The examiner respectfully disagrees.

8. In response to applicant’s argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., beginning with a fully formed purine or pyrimidine scaffold and appending substituents thereto) are not recited in the rejected claim(s). There is no limitation in the instant claims that the purine or pyrimidine scaffold be fully formed before the contacting step. Applicant argues that the step recited as “contacting a purine or pyrimidine heterocyclic scaffold” reflects a fully formed scaffold (Response, page 4, middle). However, it is the examiner’s position that this language does not limit the claim to the situation where the purine or pyrimidine scaffold is fully formed before the contacting step. All that is necessary to meet the limitations of the claim is to contact a scaffold with a mixture of chemical substituents to form a “substituent-appended scaffold”. Gordeev et al disclose this and thus the reference anticipates the claims.

9. Moreover, as stated previously, the claimed method is a method comprising. See MPEP 2111.03: The transitional term “comprising”, which is synonymous with

“including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Thus, because the claims do not specifically recite beginning with a fully formed scaffold and additional, unrecited method steps may be included, the examiner deems that the disclosure of the Gordeev et al reference reads on the instant claims.

10. Applicant argues that since the Gordeev et al reference does not anticipate claims 31, 32, 34-36, 38, 39, 41-43 and 45-49, the combination of the Gordeev et al and Smith et al references also does not render claims 31-50 obvious. The examiner maintains that the Gordeev et al reference anticipates the claims as discussed above and thus also deems that the combination of the Gordeev et al and Smith et al references is proper. Thus, the rejection under 35 U.S.C. 103(a) is also maintained.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (571) 272-0805. The examiner is on an increased flextime schedule; the best time to contact the examiner is Monday-Friday from 7:00-11:00 a.m.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
February 6, 2004

A handwritten signature in black ink, consisting of stylized, cursive letters that appear to read 'MB' followed by a long horizontal flourish.

MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER